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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,055

02/18/2004

Stephen Johnston

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EXAMINER

MCGILLEM, LAURA L

ART UNIT

PAPER NUMBER

1636

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DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,055

Applicant(s)

JOHNSTON ET AL.

Examiner

Laura McGillem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/26/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-20, 22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 24-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-14 is/are allowed.
- 6) ☒ Claim(s) 4-11, 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

It is noted that claims 4-7 and 12-15 have been amended and claims 1-3, 21 and 23 are cancelled in the amendment filed 2/26/2007. It is noted that withdrawn claims 22 and 24 have also been amended. Claims 22, 24-35 are withdrawn. Claims 4-20 are under examination.

Claim Rejections - 35 USC § 112

Applicant's arguments, see REMARKS (page 7-8), filed 2/26/2007, with respect to the rejection of claims 4-5 due to the phrase "downstream promoter element" have been fully considered and are persuasive. "Downstream promoter element" or DPE does appear to be a term known in the art.

Claims 4-5 have been amended to remove the phrase "upstream promoter element" therefore the rejection with regard to the phrase "upstream promoter element" is moot.

Applicant's arguments, see REMARKS (page 9), filed 2/26/2007, with respect to the rejection of claims 4-5 due to the phrase "CBP binding element" have been fully considered and are persuasive. The specification does also disclose the sequence of the CBP binding element as CCAATT, which the skilled artisan would recognize as a CAT sequence. The rejection of claims 4-20 under 35 U.S.C. 112, second paragraph has been withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-11 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is being maintained for reasons of record in the previous Office Action, mailed 10/31/20067 and for reasons outlined below.

Applicants submit that current independent claim 4 is directed to a nucleic acid segment comprising a synthetic promoter/enhancer or the complement of such a promoter/enhancer, wherein the segment comprises a promoter sequence comprising regions encoding promoter elements including a TATA box, a TFIIB binding element, an initiator, a downstream promoter element, and at least an SP1 binding element upstream of the TATA box and an IRF binding element upstream of the TATA box. Applicants submit that SEQ ID NOs: 35, 36, and 37 each disclose a nucleic acid segment comprising a synthetic promoter/enhancer encompassed by claim 4. Applicants submit that the Examiner has not provided reasoning as to why three members of the genus are not representative.

Applicants submit that the Action's assertion that the specification does not provide an indication of how the sequences of SEQ ID NOs: 35-37 are representative of

other promoter/enhancer sequences is incorrect. Applicants submit that SEQ ID NO:35 is an exemplary promoter comprising several binding elements of IRF-1, AP 1; NFkB, SP1; CBP; TFIIB, AP2; the TATA box (TFIID); an initiator; and a downstream promoter element (see page 8, lines 11-27 of the specification). Applicants submit that an example of a rationally designed and chemically synthesized artificial promoter/enhancer, which encompasses the exemplary promoter of SEQ ID NO:35, is represented by SEQ ID NO:36. SEQ ID NO:37 is the same as the sequence of SEQ ID NO:36, less the sterol response element (SRE). Applicants submit that the exemplary chemically synthesized promoters disclosed were designed such that each construct was centered by a TATA box with the initiator at position +1 (see specification page 26, lines 10-23). Applicants submit that various transcription factors binding sites and other elements were added upstream and downstream of the TATA box in the examples. Applicants submit that these sites and elements are underlined and indicated in parenthesis, after each specific sequence in Examples 1- 3 in the specification, which provide greater detail of the structures of SEQ ID NOs: 35-37. Applicants submit that thus the specification provides a detailed description of how SEQ ID NOs: 35-37 are representative of other promoter/enhancer sequences encompassed by the current claims.

Applicants submit that the synthetic promoter/enhancer of the currently claimed invention can be synthesized using promoter elements known to the skilled artisan (see specification .p. 8, ln. 18-27; Table 1). Applicants submit that the structures (i.e. the sequences) of these elements are described in the specification at, for example,

Examples 1-3. Applicants submit that the structure and function of these elements have been described in the literature as indicated in Table 1 and in Examples 1-3 in the specification. Applicants submit that the positional effect on gene expression for the TATA box; initiator; downstream promoter element; TFIIB recognition element; and AP1, IFN, SP1, c-Jun, SP1, NF- κ B, CBP, CREB/ATF, NF1, ISRE, AP2, Octamer, AP4, MyB, ATF, and VD binding elements; is described in Examples 5-10 of the specification. Thus, this information, along with the information regarding SEQ ID NOs: 35-37 discussed above, satisfy the written description requirement for a genus through the disclosure of the relevant identifying characteristics of the members of the genus coupled with a known or disclosed correlation between function and structure.

Applicants submit that the Action's assertion that the claims encompass a very broad genus of downstream promoter elements is unclear because the downstream promoter element refers to a particular promoter element described by Burke et al (see section B.2. above). Applicants submit that the Action's assertion that the claims encompass a very broad genus of upstream binding elements is believed to be moot in view of the fact that the phrase "upstream binding elements" is no longer recited in the claims. Rather, current claim 4 recites that the promoter/enhancer comprises "at least an SP1 binding element upstream of the TATA box and an IRF binding element upstream of the TATA box."

Applicants submit that the specification provides a detailed description of a representative number of species in the promoter/enhancer sequences of SEQ ID NOs: 35-37. Applicants submit that the present specification describes the claimed invention

in sufficient detail that the skilled artisan can reasonably conclude that the Applicants had possession of the claimed invention at filing.

Applicant's arguments filed 2/26/2007 have been fully considered but they are not persuasive. The claims are drawn to a nucleic acid segment comprising a promoter/enhancer comprising regions encoding elements including a TATA box, a TFIIB binding element, an initiator, a downstream promoter element, at least an SP1 binding element and an IRF binding element upstream of the TATA box. As written, the claimed nucleic acid segment does not recite any specific sequences for these elements, which allows the broadest reasonable interpretation of the claims. Beyond location of the downstream promoter element and SP1 binding element and IRF binding element as upstream of the TATA box, there is no limitation of the order of these elements in the nucleic acid segment recited in the claim. There is no limitation for the length of the nucleic acid segment or how far apart the elements can be from one another. The claim recites "comprising" which is open language meaning that the nucleic acid segment comprising a synthetic promoter/enhancer can also include other sequences. As written, the claimed nucleic acid sequence is very broad and encompasses not only the specifically disclosed sequences but also a large genus of possible nucleic acid segments comprising a synthetic promoter/enhancer or the complement of such a promoter/enhancer as described above.

The specification describes and exemplifies three artificial promoter/enhancers as SEQ ID NO:35, SEQ ID NO:36, and SEQ ID NO:37. However, SEQ ID NO:35 appears to be a component of SEQ ID NO:37 and SEQ ID NO:37 is the same as the

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sequence of SEQ ID: NO:36, less the sterol response element (SRE). While SEQ ID NO:35 is a specific exemplification of the claimed sequence, SEQ ID NO:36 and SEQ ID NO:37 include the sequence of SEQ ID NO:35 and therefore the core structure of the promoter/enhancer is the same, which is the reason that three members of the genus are not representative. Since the genus of the nucleic acid segment comprising the claimed elements is so broad, even the detailed description of how SEQ ID NOs: 35-37 is not representative of other promoter/enhancer sequences encompassed by the current claims.

Although "downstream promoter element" has been established as term known in the art, this element is still a component of a very broadly claimed nucleic acid segment. While the phrase "upstream binding elements" has been amended out of the recitation of the claim, the limitation of the SP1 and IRF binding elements has been amended so that they are upstream of the TATA box. However, the claimed nucleic acid segment is still broad and encompasses a nucleic acid segment comprising a promoter/enhancer wherein SP1 and IRF binding elements can be anywhere on the nucleic acid segment and at any distance from the other elements as long as they are upstream of the TATA box.

Therefore, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variant of the genus and is insufficient to support them.

Claim Rejections - 35 USC § 102

Applicants have cancelled claims 2-3, and have amended claims 4 and 12 to independent form.

In light of the cancellation of claims 2-3, the rejection of claims 2, 6, 15 and 17-19 under 35 U.S.C. 102(b) as being anticipated by Matthews et al has been withdrawn.

In light of the cancellation of claims 2-3, the rejection of claims 2, 6-11, 15 and 17-20 under 35 U.S.C. 102(a) as being anticipated by Parks et al has been withdrawn.

In light of the cancellation of claims 2-3, the rejection of claims 2, 15 and 17-19 under 35 U.S.C. 102(e) as being anticipated by Roninson et al has been withdrawn.

In light of the cancellation of claims 2-3, the rejection of claims 2, 15 and 17- 20 under 35 U.S.C. 102(e) as being anticipated by Price et al has been withdrawn.

In light of the cancellation of claims 2-3, the rejection of claims 2 and 15-20 under 35 U.S.C. 102(e) as being anticipated by Krohn et al as evidenced by Matthews et al has been withdrawn.

In light of the cancellation of claims 2-3, the rejection of claims 2-3, 15 and 17-20 under 35 U.S.C. 102(e) as being anticipated by Berger et al has been withdrawn.

Conclusion

Claims 12-14 are allowed. Claims 4-11 and 15-20 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571)272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
Examiner
5/14/2007

CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written over a horizontal line.